


25. Mai 2022 / BA


www.fehling-instruments.de

Urgent safety information
Warning about germ-loaded secondary packaging
regarding
Sterile FENESTRA and FORMAR cervical disc replacement

Dear Sir or Madam,

according to our records we have delivered products to you which are affected by this Urgent Safety Information and therefore we kindly ask you to pay attention to it.

Identification of affected medical devices:

FENESTRA cervical disc replacement PEEK sterile, according to attachment
FORMAR cervical disc replacement PEEK sterile, according to attachment

Description of the problem including the identified cause:

The cervical disc replacement supplied by FEHLING in sterile condition are packaged as follows:

- primary packaging: Blister/Tyvek
- secondary packaging: Peel bag
- outer packaging: folding box

A current transport validation of the sterile packaging of the cervical disc replacement has shown that the sealing seam of the secondary packaging can be damaged during transport and that germs can penetrate the secondary packaging as a result.

The primary packaging has not suffered any damage, which is why the implants remain germ-free and sterile.

As the damage to the secondary packaging is not necessarily visible, there is a risk that germs will be transferred from the outside of the primary packaging to the implant when the primary packaging is opened. This can induce inflammations/infections in the patient. There is no danger to users or other persons.

If patients are implanted with a germ-loaded implant, they should continue to be followed up according to the standard protocol of their medical facility. If no inflammation/infection occurs, there are no further risks for the patient.

What measures are to be taken by the addressee?

To avoid risks for the patient, it is mandatory to observe the following instruction:

After opening the primary packaging, the implant must not be removed with the hands, but must be placed onto the instrument table without touching it or it must be picked up with suitable forceps. This prevents germs on the outside of the primary packaging from being transferred to the implant or other instruments.

Patients who had surgery until the measure is implemented must be followed up according to the standard protocol of their medical facility.

Measures of FEHLING INSTRUMENTS GmbH & Co. KG

To avoid damaging of the secondary packaging in the future, we will change the packaging of the HWS cages. The change of the sterile packaging of the HWS cages including the necessary validations will take approx. 3 months. Until then, it is mandatory to follow the procedure described above.

Disclosure of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information.

If you have given the products to other persons, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the action has been completed.

The "Bundesinstitut für Arzneimittel und Medizinprodukte" has received a copy of this "Urgent Safety Information".

Contact person:

If you have any questions about the process, please contact the following person:

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63791 Karlstein
Germany
www.fehling-instruments.de

Anna Misterek
Tel.: +49 6188-9574-0
vigilance@fehling-instruments.de

Best Regards

FEHLING INSTRUMENTS GmbH & Co. KG

[REDACTED]

Attachment
List of affected products
Confirmation form

Attachment: List of affected products

Nr	GTIN	Description
PA-3S	4058749000450	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 3 mm, sterile
PA-4S	4058749000467	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 4 mm, sterile
PA-5S	4058749000474	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 5 mm, sterile
PA-6S	4058749000481	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 6 mm, sterile
PA-7S	4058749000498	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 7 mm, sterile
PA-8S	4058749000504	FENESTRA cerv. disc replacem., PEEK 15 x 12 x 8 mm, sterile
PB-3S	4058749000511	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 3 mm, sterile
PB-4S	4058749000528	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 4 mm, sterile
PB-5S	4058749000535	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 5 mm, sterile
PB-6S	4058749000542	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 6 mm, sterile
PB-7S	4058749000559	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 7 mm, sterile
PB-8S	4058749000566	FENESTRA cerv. disc replacem., PEEK 15 x 14 x 8 mm, sterile
PC-3S	4058749000573	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 3 mm, sterile
PC-4S	4058749000580	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 4 mm, sterile
PC-5S	4058749000597	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 5 mm, sterile
PC-6S	4058749000603	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 6 mm, sterile
PC-7S	4058749000610	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 7 mm, sterile
PC-8S	4058749000627	FENESTRA cerv. disc replacem., PEEK 17 x 14 x 8 mm, sterile
PD-3S	4058749000634	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 3 mm, sterile
PD-4S	4058749000641	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 4 mm, sterile
PD-5S	4058749000658	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 5 mm, sterile
PD-6S	4058749000665	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 6 mm, sterile
PD-7S	4058749000672	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 7 mm, sterile
PD-8S	4058749000689	FENESTRA cerv. disc replacem., PEEK 17 x 16 x 8 mm, sterile
PE-4S	4058749000696	FENESTRA cerv. disc replacem., PEEK 19 x 16 x 4 mm, sterile
PE-5S	4058749000702	FENESTRA cerv. disc replacem., PEEK 19 x 16 x 5 mm, sterile
PE-6S	4058749000719	FENESTRA cerv. disc. replacem. PEEK 19 x 16 x 6 mm, sterile
PE-7S	4058749000726	FENESTRA cerv. disc. replacem. PEEK 19 x 16 x 7 mm, sterile
PE-8S	4058749000733	FENESTRA cerv. disc. replacem. PEEK 19 x 16 x 8 mm, sterile
PL-4S	4058749000740	FENESTRA cerv. disc replacem., PEEK 13 x 12 x 4 mm, sterile
PL-5S	4058749000757	FENESTRA cerv. disc replacem., PEEK 13 x 12 x 5 mm, sterile
PL-6S	4058749000764	FENESTRA cerv. disc replacem., PEEK 13 x 12 x 6 mm, sterile
PM-4S	4058749000771	FENESTRA cerv. disc replacem., PEEK 13 x 14 x 4 mm, sterile
PM-5S	4058749000788	FENESTRA cerv. disc replacem., PEEK 13 x 14 x 5 mm, sterile
PM-6S	4058749000795	FENESTRA cerv. disc replacem., PEEK 13 x 14 x 6 mm, sterile
PN-4S	4058749000801	FENESTRA cerv. disc replacem., PEEK 19 x 18 x 4 mm, sterile
PN-5S	4058749000818	FENESTRA cerv. disc replacem., PEEK 19 x 18 x 5 mm, sterile
PN-6S	4058749000825	FENESTRA cerv. disc replacem., PEEK 19 x 18 x 6 mm, sterile

Nr	GTIN	Description
PN-7S	4058749000832	FENESTRA cerv. disc replacem., PEEK 19 x 18 x 7 mm, sterile
PN-8S	4058749000849	FENESTRA cerv. disc replacem., PEEK 19 x 18 x 8 mm, sterile
PO-5S	4058749000856	FENESTRA cerv. disc replacem., PEEK 13 x 16 x 5 mm, sterile
PP-4S	4058749000863	FENESTRA cerv. disc replacem., PEEK 15 x 16 x 4 mm, sterile
PP-5S	4058749000870	FENESTRA cerv. disc replacem., PEEK 15 x 16 x 5 mm, sterile
PP-6S	4058749000887	FENESTRA cerv. disc replacem., PEEK 15 x 16 x 6 mm, sterile
PQ-5S	4058749000894	FENESTRA cerv. disc replacem., PEEK 17 x 18 x 5 mm, sterile
PQ-6S	4058749000900	FENESTRA cerv. disc replacem., PEEK 17 x 18 x 6 mm, sterile
PR-6S	4058749000917	FENESTRA cerv. disc replacem., PEEK 19 x 14 x 6 mm, sterile
PS-5S	4058749000924	FENESTRA cerv. disc replacem., PEEK 21 x 16 x 5 mm, sterile
PS-6S	4058749000931	FENESTRA cerv. disc replacem., PEEK 21 x 16 x 6 mm, sterile
PH-7S	4058749001082	FORMAR cerv. disc replacement PEEK, 18x14x7mm, sterile
PH-6S	4058749001075	FORMAR cerv. disc replacement PEEK, 18x14x6mm, sterile
PH-5S	4058749001068	FORMAR cerv. disc replacement PEEK, 18x14x5mm, sterile
PH-4S	4058749001051	FORMAR cerv. disc replacement PEEK, 18x14x4mm, sterile
PG-7S	4058749001037	FORMAR cerv. disc replacement PEEK sterile, 16 x 14 x 7 mm
PG-6S	4058749001020	FORMAR cerv. disc replacement PEEK sterile, 16 x 14 x 6 mm
PG-5S	4058749001013	FORMAR cerv. disc replacement PEEK sterile, 16 x 14 x 5 mm
PG-4S	4058749001006	FORMAR cerv. disc replacement PEEK sterile, 16 x 14 x 4 mm
PG-3S	4058749000993	FORMAR cerv. disc replacement PEEK sterile, 16 x 14 x 3 mm
PF-7S	4058749000986	FORMAR cerv. disc replacement PEEK sterile, 14 x 13 x 7 mm
PF-6S	4058749000979	FORMAR cerv. disc replacement PEEK sterile, 14 x 13 x 6 mm
PF-5S	4058749000962	FORMAR cerv. disc replacement PEEK sterile, 14 x 13 x 5 mm
PF-4S	4058749000955	FORMAR cerv. disc replacement PEEK sterile, 14 x 13 x 4 mm
PF-3S	4058749000948	FORMAR cerv. disc replacement PEEK sterile, 14 x 13 x 3 mm

CONFIRMATION FORM	
Please return by e-mail to	
vigilance@fehling-instruments.de	
FSN-NR.:	22-010
FSN date:	2022-05-25
Product	Sterile FORMAR and FENESTRA cervical disc replacement
Customer	
Customer number	
Name	
Address	
Contact person	
Phone number	
E-mail	
Measures to be taken by the customer	
<input type="checkbox"/>	I acknowledge receipt of the FSN and confirm that I have read and understood its contents.
<input type="checkbox"/>	I have carried out all actions required by the FSN.
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and have been carried out.
Name	
Date	
Signature	